CERVICAL HEALTH:

A Guide for Screening Programs

Texas Department of Health
Bureau of Women's Health
Breast and Cervical Cancer Control Program

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A Guide for Screening Programs
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Cervical Health:
A Guide for Screening Programs of the Texas Department of Health
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Statement of Need

In Texas, 1,000 women will be diagnosed with cervical cancer in 2001. Early detection can prolong life, yet hundreds of women will die from cervical cancer in Texas this year. The burden will fall more heavily on low-income, minority, and rural women who have less access to care. With increased screening and early detection, Texas women may live longer with an improved quality of life.

In order to assure quality screening and diagnostic services for Texas women, the following protocol was developed by Texas Department of Health staff, work group members, and interested physicians. Sources used include the Centers for Disease Control and Prevention guidelines, National Cancer Institute, American Cancer Society, and the University of Texas M.D. Anderson Cancer Center for the development of this protocol.

I. Screening for Cervical Cancer

Definition: Screening is the attempt to detect unsuspected disease in an asymptomatic woman. (See glossary)

Purpose: The purpose of cervical screening is to improve survival through early detection of cancerous and pre-cancerous lesions of the cervix.

Methods: The methods used for early detection and screening of cervical cancer are the pelvic examination and the Papanicolaou test (Pap test).

A. Client Education

Client education must be documented. Teaching materials should be provided to the woman on cervical cancer, pelvic examinations, and Pap tests to reinforce staff recommendations. At a minimum materials should include:

- Written and verbal information in a woman's primary language on pelvic examinations, Pap tests, Human Papilloma Virus (HPV), and protected or monogamous sexual practices;

- Information about when to call a provider about signs or symptoms of cervical cancer;

- The importance of adherence to recommended screening guidelines; and

- An explanation of procedures (pelvic examination and Pap test) and the clinic process.

Note: Limitations of screening:

- Normal results on screening examination do not necessarily indicate absence of disease. No screening test is 100 percent accurate. Therefore, some cases of the disease will be missed.

- Normal results never rule out the later development of disease, which is why ongoing regular screening is strongly recommended.

- An abnormal finding does not necessarily mean it is cancerous.

B. Clinical Examination

The examination should be conducted in a setting allowing for minimal distraction and adequate privacy for the woman. Examination gowns should be adjusted to minimize unnecessary exposure of the woman. Examinations should not be rushed; a complete pelvic examination will last from five to ten minutes. As part of the pelvic examination, a complete history should include:

$ Date and results of the last pelvic examination and Pap test;

$ Date and results of any previous pelvic surgery, chemotherapy, and/or radiation therapy;

$ Date of last menstrual period and history of pregnancies;

$ History of medications including oral contraceptives and hormonal replacement therapy;

$ Risk factors for cervical cancer; and

$ Description of present pelvic symptoms, if any (pain, discharge, abnormal bleeding, lymph node enlargement in groin area).

The following are the American Cancer Society, American College of Gynecologists and National Cancer Institute's screening recommendations for cervical cancer:

> *All women who are, or who have been, sexually active, or have reached age 18, should have an annual Pap test and pelvic examination. After a woman has had three or more consecutive satisfactory normal annual examinations, the Pap test may be performed less frequently at the discretion of her physician.*

Screening is not required for women that have had three consecutive, annual, normal, Pap tests and pelvic examinations within the last five years. The Pap test and pelvic examination may be performed less frequently at the discretion of the woman and her physician.

The Breast and Cervical Cancer Control Program recommends that women who are considered to be at high risk may be screened annually at the discretion of her clinician. This may include women with multiple sexual partners, a history of dysplasia, Human Papilloma Virus, Human Immuno-deficiency Virus (HIV), or who are immuno-compromised.

Annual screening may be discontinued for women 65 or older with two normal Pap test results within the last five-year period and who are at low risk for cervical cancer.

A Pap test using an FDA approved liquid based technology may be indicated for a woman who has never been screened or who has not been screened for three or more years.

- A comprehensive assessment should include Clinical Breast Examination, pelvic examination and a Pap test:
    - Clinical Breast Examination (Refer to the "Breast Health: A Guide for Screening Programs" for performing the Clinical Breast Exam and for follow-up recommendations if an abnormality is detected.);
    - Assessment of the abdomen;
    - Assessment of the external genitalia;
    - Visual assessment of the cervix and collection of cervical cells for cytological analysis (Pap test);
    - Visual inspection of the vaginal vault during withdrawal of the speculum and the bimanual examination; and

- Recto/vaginal examination.

- A recommended guide to performing the pelvic examination and Pap test is in Appendix A.

- Documentation of any physical findings of the pelvic examination.

- All abnormal pelvic examination findings should be referred for appropriate medical follow-up.

II. Follow-up Routine

General summary: Either an abnormal pelvic examination or Pap test requires follow-up. **A normal Pap test does not rule out cancer if a woman has a cervical lesion on pelvic examination.**

A. Normal screening examination (pelvic and Pap)

A negative Pap test needs no further diagnostic workup. The health provider should notify a woman of findings, including the need for continued screening examinations. After a woman has had three or more consecutive satisfactory normal annual examinations, the Pap test may be performed less frequently at the discretion of her physician.

B. Abnormal Pap test

For women with Atypical Squamous Cells of Undetermined Significance, (ASCUS), or Low Grade Squamous Intraepithelial Lesion, (LGSIL), two abnormal Pap tests must be documented before a woman can be referred for colposcopy. These women must be followed with a repeat Pap test in three to six months and she should have at least two or three **normal** Pap test results in a three to six month period before regular annual screening resumes. Most of these abnormalities will resolve spontaneously without treatment. Women with High Grade Squamous Intraepithelial Lesion (HGSIL) Pap results must be referred for colposcopy. A Pap test should be repeated prior to colposcopy if the last abnormal Pap test result is more than three months old.

C. Contact and Documentation

The health care provider must **initiate** attempts to notify a woman regarding her abnormal **screening** result and the implications of the pelvic and Pap screening examination within five (5) working days after **receipt** of the abnormal result. For abnormal **diagnostic** results, an attempt to notify the woman must be made within two (2) working days after **receipt** of the abnormal finding. If an agency has a protocol in place that states the client

will receive a return appointment two weeks post colposcopy to receive diagnostic results; provider may note that visit as the first attempt to contact the client. A system should be in place to ensure the receipt of results in a timely manner.

Information given to the woman should include:

- The nature of the suspected abnormality;
- The need for further testing before treatment (if appropriate);
- A choice (if available) of appropriate referrals for definitive diagnostic procedures; and
- The opportunity to discuss her needs and responsibility in regard to obtaining follow-up care (see Case Management).

The health care provider must attempt to notify the woman and document those attempts. The final attempt should be by certified mail. After a minimum of three unsuccessful attempts to notify a woman with abnormal **screening** results, she may be considered "lost to follow-up." For abnormal **diagnostic** results, if contact is not made within **two working days**, the provider must develop a plan of action based on the severity of the results. Action should be taken as soon as possible.

III. Clinical Management of Abnormal Findings

Purpose: To determine the nature of cervical disease, in particular cancer, by further diagnostic procedures and pathologic confirmation.

A. Infection/Inflammation/Reactive Changes

These are cellular changes that are usually or most often caused by infection (viral, bacterial, protozoan, or fungal) or by estrogen deficiency in postmenopausal women. The underlying cause should be identified and treated, if indicated. Following treatment, the Pap test may be repeated in three months. If inflammation persists in spite of treatment, the woman should be referred for colposcopy.

B. Atypical Squamous Cells of Undetermined Significance (ASCUS)

ASCUS is interpreted as cellular changes that have an atypical appearance. These changes may be due to an inflammatory process, estrogen deficiency (as in a post-menopausal woman), or dysplastic changes. The cytology report should contain an opinion from the cytopathologist as to which of the above reasons are responsible for the

atypical cellular changes (if possible). The underlying cause (if it can be determined) may be treated, and the Pap test repeated. If the repeat Pap test returns with ASCUS, the woman must be referred for colposcopy.

C. Low grade SIL (CIN I and HPV changes)

This is mild dysplasia (CIN I) or cellular changes due to the HPV. Mild dysplasia is characterized by definite abnormalities in nuclear development, with retention of an essentially normal cytoplasm. The clinician must repeat the Pap test in three to six months for clients with CIN I or HPV changes before referring for colposcopy, as many of these (approximately 60-85%) will resolve spontaneously without treatment. The woman must be referred for colposcopy if the repeat Pap test is abnormal.

D. High grade SIL (CIN II, CIN III and Carcinoma in situ)

With moderate dysplasia, the cell nucleus shows further signs of abnormal development and some abnormalities in the cytoplasm. Severe dysplasia is characterized by severe changes in development of the cell as well as loss of normal structure of the cells' arrangement into tissue. Invasion of the basement membrane can occur at any phase of CIN, but it is more likely to occur at CIN III. **The woman must be referred for colposcopy.** A biopsy must be performed to determine if invasion has occurred.

E. Squamous cell cancer

Cancerous cells have probably invaded through the basement membrane and into the cervical stroma, where the cells have access to blood and lymph vessels, enabling them to metastasize throughout the body. The woman should be referred for further evaluation to determine the extent of the invasion.

F. **AGUS** (Atypical glandular cells of undetermined significance)

The cytological report should include the probable site of origin (endometrial or endocervical). The woman must be referred for further evaluation, which must include one or more of the following:

- colposcopy;
- endometrial biopsy;
- Loop Electrosurgical Excision Procedure (LEEP).

G. Other Findings

1. Adenocarcinoma

Adenocarcinoma of the uterine cervix is a malignant neoplasm of epithelial cells in a glandular or glandlike pattern. The cytology report should include the probable site of origin (endometrial, extrauterine, or endocervical). Most adenocarcinoma occurs within the endocervical canal and carries a poorer prognosis than squamous carcinoma especially if lymph nodes are involved. The woman should be referred immediately.

2. Glassy cell carcinoma

A variant of adeno-squamous carcinoma, glassy cell carcinomas contain sheets of large malignant epithelial cells with abundant cytoplasm with a "ground glass" appearance. This condition responds poorly to radiation therapy and has a much poorer prognosis than squamous cell carcinoma. The woman should be referred immediately.

3. Small cell neuroendocrine carcinoma

Highly aggressive and metastasizing early, small cell neuroendocrine carcinoma histologically resembles small cell carcinomas of the lung (oat cell carcinomas). The woman should be referred immediately.

IV. SPECIAL CONSIDERATIONS

A. Pregnant Women

Pregnant women may be screened for cervical cancer using the same guidelines and techniques as non-pregnant women **EXCEPT** that a pregnant woman should have the endocervical sample taken with a saline moistened cotton swab or cervical broom instead of a cytobrush. A pregnant woman whose Pap test returns with abnormalities should be referred for colposcopy and biopsy. She should be monitored periodically throughout the pregnancy, and re-evaluated after delivery of the baby.

B. Woman with a History of Hysterectomy

Approximately 35 percent of women age 50 and older have had a hysterectomy. They are not at risk for developing cervical cancer and should not be screened for cervical cancer **UNLESS** the hysterectomy was for a **cervical neoplasm**. A woman who has had a "supracervical hysterectomy" is at risk for cervical cancer and should be screened according to recommended guidelines.

APPENDIX A

PROCEDURE FOR COLLECTING A PAP TEST

PROCEDURE FOR OBTAINING THE PAP TEST FROM THE M.D. ANDERSON CANCER CENTER CERVICAL SCREENING CLINIC

I. Conditions that should be met before taking the Pap test:

- Intact cervix (or hysterectomy for cancer).
- No intercourse, menstruation, douches, or vaginal medications for the past 24 hours.
- Perform the Pap test before taking other tests or cultures.
- Perform the Pap test before the bimanual pelvic examination.

II. Initial examination

$ Explain procedure to the woman.
$ Write woman's full name and birth date on frosted end of glass slide with a #2 pencil.
$ Inspect the external genitalia. Do not clean the cervix prior to sampling.
$ Lubricate speculum and visually examine cervix and vaginal walls.
$ Identify cervical os and squamo-columnar junction (if possible).

III. Obtaining ectocervical and endocervical specimens

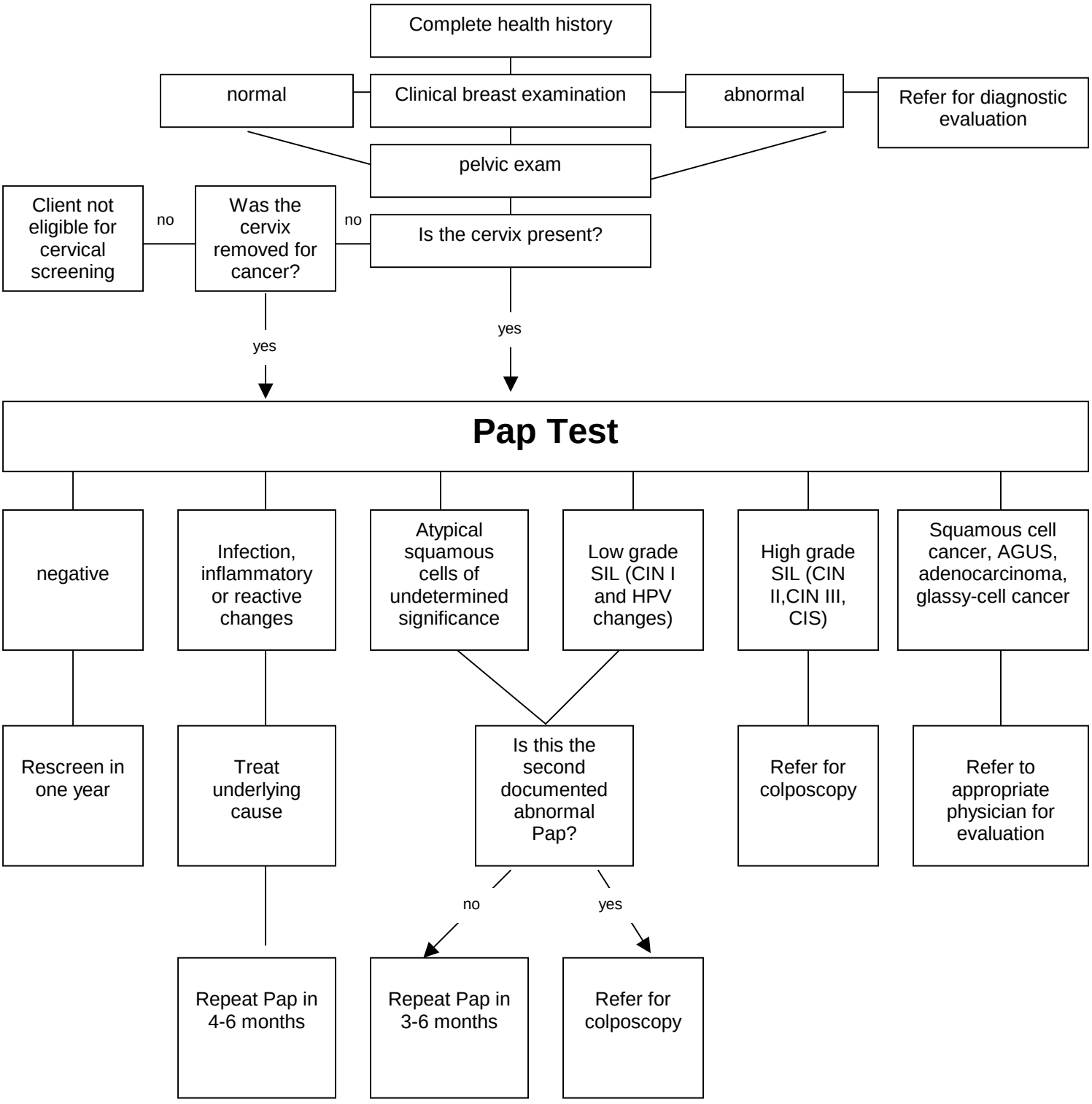
$ Apply spatula to cervix with mild pressure and scrape around the cervix so that squamo-columnar junction is well sampled. If squamo-columnar junction is not clearly identified, be sure the entire ectocervix is well sampled.
$ Hold spatula in opposite hand while collecting the endocervical specimen.
$ To collect the endocervical specimen, the cytobrush is the preferred instrument. For pregnant patients, use a saline moistened Q-tip swab. (Moistening the swab decreases absorption of the specimen into the cotton). Insert cytobrush or saline moistened swab into cervical os. Roll brush or swab between your thumb and index finger, clockwise, and counterclockwise. Remove swab or brush.
$ Place spatula on slide and spread a thin film onto the slide using several strokes and both sides of the spatula.
$ Roll the endocervical specimen from the brush or swab onto the slide on top of the ectocervical sample.
$ Immediately (within 5 seconds) apply fixative to prevent air drying by holding spray nozzle approximately 10 inches from slide.

IV. Continue with the pelvic examination, including a bimanual examination.

APPENDIX B

MANAGEMENT OF CERVICAL SCREENING

Management of Cervical Screening



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APPENDIX C

GLOSSARY

GLOSSARY

Adjuvant Therapy: Treatment that is given in addition to the primary treatment. This is generally chemotherapy for patients with cancer treated with radiotherapy.

Biopsy: The removal of a sample of tissue that is examined under the microscope to see if cancer cells are present. Removing tissue or fluid with a needle is called needle biopsy or aspiration.

Cervical os: The opening in the cervix that leads into the uterine cavity.

Colposcopy: Examination of the vagina and the cervix with a magnifying instrument known as a colposcope.

Cryotherapy: Destruction of tissue by the application of extreme cold.

Dysplasia: Abnormal growth or development of cells.

Ectocervix; Exocervix: The outside, visible portion of the cervix.

Endocervix: The mucous membrane lining the canal of the cervix. Sometimes referred to as the endocervical canal.

Electrocautery: An apparatus for cauterizing tissue, consisting of a platinum wire in a holder which is heated to a red or white heat when the instrument is activated by an electric current.

Incidence: The number of instances of illness commencing during a given period in a specified population. More generally, the number of new cases of a disease in a defined population, within a specified period of time.

In-situ: Pre-invasive stage of a malignant growth. A change where highly atypical cells are localized and confined to the basement epithelial membrane of the cervix; they have not invaded surrounding tissue.

Loop Electrosurgical Excision Procedure (LEEP) The use of thin wire loop electrode that allows CIN lesions to be entirely removed for histopathologic analysis.

Negative predictive value: The proportion of cases with a negative test that are found by diagnostic evaluation to not have the disease in question. The higher the negative predictive value, the lower the number of false-negative results. (e.g. If one hundred non-diseased persons are tested and 98 have negative results then the test is said to have a 98% negative predictive value.)

Positive predictive value: The proportion of cases with a positive test that are found by diagnostic evaluation to have the disease in question. The higher the positive predictive value, the lower the number of false-positive results. (e.g. 10 cancers out of 100 abnormal cases equals a positive predictive value of 10%)

Prevalence: The number of instances of a given disease (e.g. cervical cancer) in a given population at a designated time.

Radiation therapy: Treatment with radiation usually follows surgery. The rationale for using radiation is to eradicate other cancer cells that may be present in the remaining tissue and decrease the chance for local cancer recurrence.

Screening: The presumptive identification of unrecognized disease.

Squamo-columnar junction: The line along which the stratified squamous epithelium meets the mucus-secreting columnar epithelium of the endocervix. It is not always visible. The location of the Squamo-columnar junction changes over time, starting out on the vaginal wall at birth and retreating up into the cervical canal by menopause. Virtually all squamous premalignant and invasive cancerous lesions occur at the squamo-columnar junction.

Sensitivity: Sensitivity is the proportion of truly diseased persons in the screened population who are identified as diseased by a screening test. Sensitivity is a measure of the probability that any given case will be identified by the test. (e.g. if thirty individuals out of one hundred has the disease and the test identifies twenty eight of them, the test is considered to have a high sensitivity.) Two individuals would have received a "false-negative" result.

Specificity: Specificity is the proportion of truly non-diseased persons who are identified as non-diseased by the screening test. It is a measure of the probability of correctly identifying a non-diseased person with a screening test. (e.g. if 98 individuals out of 100 do not have the disease and the test comes back negative on 90 individuals, the test is considered to have a high specificity.) Eight individuals would have received a "false-positive" result.

Ultrasound: High-frequency sound waves forming a pattern of echoes that are electronically translated into a visual image.

APPENDIX D

THE BETHESDA REPORTING SYSTEM FOR PAP SMEAR RESULTS

The 1988 Bethesda System for Reporting Cervical/Vaginal Cytological Diagnosis

NEGATIVE (Within normal limits)

INFECTION

- Fungal
  - Fungal organisms morphologically consistent with *Candida* species
  - Other
- Bacterial
  - Microorganisms morphologically consistent with *Gardnerella* species
  - Microorganisms morphologically consistent with *Actinomyces* species
  - Cellular changes suggestive of *Chlamydia* species infection, subject to confirmatory studies
  - Other
- Protozoan
  - *Trichomonas vaginalis*
  - Other
- Viral
  - Cellular changes associated with cytomegalovirus
  - Cellular changes associated with herpesvirus simplex
  - Other
  - (Note: for human papillomavirus [HPV], refer to "Epithelial Cell Abnormalities, Squamous Cell")
- Other

REACTIVE AND REPARATIVE CHANGES

- Inflammation
  - Associated cellular changes
  - Follicular cervicitis
- Miscellaneous (as related to patient history)
  - Effects of therapy
  - Ionizing radiation
  - Chemotherapy
  - Effects of mechanical devices (eg, intrauterine contraceptive device)
  - Effects of nonsteroidal estrogen exposure (eg, diethylstilbestrol)
  - Other

EPITHELIAL CELL ABNORMALITIES

- *Squamous cell*
  - Atypical squamous cells of undetermined significance (recommended for follow-up and/or type of further investigation: specify)

- Squamous intraepithelial lesion (SIL) (comment of presence of cellular changes associated with HPV if applicable)
    - Low-grade squamous intraepithelial lesion, encompassing:
        - Cellular changes associated with HPV
        - Mild (slight) dysplasia/cervical intraepithelial neoplasia grade 1 (CIN 1)
    - High-grade squamous intraeithelial lesion, encompassing:
        - Moderate dysplasia/CIN 2
        - Severe dysplasia/CIN 3
        - Carcinoma in situ/CIN 3
- Squamous cell carcinoma

Glandular Cell

- Presence of endometrial cells in one of the following circumstances:
    - Out of phase in a menstruating woman
    - In a postmenopausal woman
    - No menstrual history available
- Atypical glandular cells of undetermined significance (recommended follow-up and/or type of further investigation: specify)
    - Endometrial
    - Endocervical
    - Not otherwise specified
- Adenocarcinoma
    - Specify probable site of origin: endocervical, endometrial, extrauterine
    - Not otherwise specified
- Other epithelial malignant neoplasm: specify

NONEPITHELIAL MALIGNANT NEOPLASM: SPECIFY

HORMONAL EVALUATION (APPLIES TO VAGINAL SMEARS ONLY)

- Hormonal pattern compatible with age and history
- Hormonal pattern incompatible with age and history: specify
- Hormonal evaluation not possible
    - Cervical specimen
    - Inflammation
    - Insufficient patient history

OTHER